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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,593	10/13/2000	Osamu Tetsu	M-9005 US	9434

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EXAMINER	
LOEB, BRONWEN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 12/04/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/687,593	TETSU ET AL.	
	Examiner	Art Unit	
	Bronwen M. Loeb	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) *22-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 October 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This action is in response to the communication filed 21 September 2001.

Claims 1-93 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 7 is acknowledged. The traversal is on the ground(s) that there is not a serious burden to search Groups I-IV together and that any search of prior art for one is expected to identify art for all the methods of Groups I-III and the cell of Group IV. This is not found persuasive because while the searches may be overlapping, they are not coextensive.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 22-93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Drawings

3. The drawings are objected to because the writing in Figure 1, particularly in the cross-hatched elements, is very difficult to read. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claim 7 is objected to because of the following informalities: Claim 7 recites "b-galactosidase (b-gal)". The correct term is β-galactosidase and β-gal. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7, 10, 19 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "said reporter gene" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 is vague and indefinite in reciting "heteromelic receptor partner". This phrase is not a term of art and is not defined in the specification.

Claim 19 is vague and indefinite in reciting "a nucleic acid". Is this the same nucleic acid as recited in claim 1 or a second nucleic acid?

Claim 21 is vague and indefinite in reciting "said cell further comprises a second nucleic acid". Since the second nucleic acid does not encode a chimeric protein but rather the ligand or metabolic product, the role of this second nucleic acid in the method of claim 1 is unclear.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 7 has been examined assuming its proper dependency is upon claim 6.

9. Claims 1, 2, 6, and 10-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Karin et al (USP 6,242,253). Karin et al teach using a two hybrid assay to screen for agents that alter the association of IκB kinase with a second protein, such as IκB or a regulatory protein. Reporter genes are taught. Screening function interactions in 293 cells is taught. See entire document, especially col. 3, lines 38-56, col. 19, line 41-col. 20, line 17, col. 21, lines 31-50, col. 25, lines 8-60, col. 26, lines 39-49 and col. 35, line 11-17.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-12 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karin et al as applied to claims 1, 2, 6, and 10-12 and further in view of Sadowski et al (USP 5,885,779), Young (Biology of Reproduction (1998) 58:302-311) and Finley et al (in The Yeast Two-Hybrid System, eds. P. Bartel, S. Fields, Oxford University Press, (1997) pp. 197-214). Karin et al does not specifically teach the two hybrid assay using a repressor protein, VP16, Gal4 or Gal4Y, reporter genes such as β-galactosidase, an apoptosis gene or cytotoxin, the two hybrid wherein the chimeric proteins are introduced into the cell or wherein the chimeric proteins are expressed by an inducible promoter. At the time the invention was made, it would have been obvious to one of ordinary skill to use any of these elements in the two hybrid assay taught by Karin et al. One of ordinary skill in the art would have been motivated to do so as these are well-known elements of the now-ubiquitous two hybrid assay. See for instance Young, pp. 302-303. Finley et al teach that inducible promoters are useful in two hybrid assays to permit transient expression of toxic proteins and they help to eliminate many

false positives. See p. 199 under "2. Interaction Mating". Sadowski et al teach the use of a transcriptional repression domain, rather than a transactivating domain, in a two hybrid and that it is preferable for use in screening for inhibitors of protein-protein interactions because it relies on a positive signal (expression of the reporter gene) rather than a negative signal. See col. 3, line 60- col. 4, line 6 and col. 5, line 13- col. 16, line 28.

13. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barker et al (USP 5,851,775), in view of Sadowski et al, Young, Finley et al, Hagahara et al (Nature Medicine (1998) 4:1449-1452) and Schwarze et al (Science (1999) 285:1569-1572). Barker et al teach using a two hybrid assay to screen for compounds that inhibit the binding of β-catenin and Tcf-4. The assays may be done in vivo or in vitro. Barker et al does not specifically teach the two hybrid assay using a repressor protein, VP16, Gal4 or Gal4Y, reporter genes such as β-galactosidase, an apoptosis gene or cytotoxin, the two hybrid wherein the chimeric proteins are introduced into the cell, or one of the chimeric proteins comprises an HIV TAT domain or wherein the chimeric proteins are expressed by an inducible promoter. At the time the invention was made, it would have been obvious to one of ordinary skill to use any of these elements in the two hybrid assay taught by Barker et al. One of ordinary skill in the art would have been motivated to do so as these are well-known elements of the now-ubiquitous two hybrid assay. See for instance Young, pp. 302-303. Finley et al teach that inducible promoters are useful in two hybrid assays to permit transient expression of toxic proteins and they help to eliminate many false positives. See p. 199 under "2.

Interaction Mating". Sadowski et al teach the use of a transcriptional repression domain, rather than a transactivating domain, in a two hybrid and that it is preferable for use in screening for inhibitors of protein-protein interactions because it relies on a positive signal (expression of the reporter gene) rather than a negative signal. See col. 3, line 60- col. 4, line 6 and col. 5, line 13- col. 16, line 28. Using an HIV TAT domain to promote internalization of proteins, or other molecules, into virtually any cell type would have been obvious to one of ordinary skill at the time of the invention. One would have been motivated to do so in order to avoid the labor-intensive transformation process and to enable use of eukaryotic cells that might be inefficiently transformed at best. See for instance Hagahara et al or Schwarze et al.

Conclusion

Claims 1-21 are rejected.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to Dianiece Jacobs, Patent Analyst whose telephone number is (703) 305-3388.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

December 3, 2001

REMY YUCEL, PH.D
PRIMARY EXAMINER